

PATENT
USSN 09/721,506
002616US; 018-210c

REMARKS

This paper is responsive to the Office Action dated June 16, 2005, which is the first action after filing the Request for Continued Examination.

Claims 73, 75-78, 80-81, 83-86, 88-89, 91-94, 96, and 101-104 were previously pending in the application. Certain claims are amended herein to standardize punctuation, without altering their meaning. Claims 73, 81, and 89 have been cancelled. Accordingly, claims 75-78, 80, 83-86, 88, 91-94, 96, and 101-104 are now pending, with claims 80, 88, and 96 withdrawn from examination.

Further consideration and allowance of the application is respectfully requested.

New matter rejection

The claims under examination stand rejected as failing to comply with the written description requirement of 35 USC § 112 ¶ 1. Specifically, the Office Action indicates that it has failed to find support for features of the claims that indicate a degree of identity between sequences and the length over which the sequences are to be compared.

In fact, these limitations were added to the claims in keeping with suggestions made by the Examiner in a previous interview. Applicants respectfully submit that the claims as currently worded are fully supported by the disclosure as originally filed, to the extent required by § 112 ¶ 1. The written description requirement does not constrain applicants to copy language into the claims directly from the disclosure as originally filed:

The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.' *Union Oil Co. of California v. Atlantic Richfield Co.*, 54 USPQ2d 1227 (Fed. Cir. 2000), citing *In re Gosteli*, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) and *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).

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In order to satisfy the written description requirement, the disclosure as originally filed need not provide *in haec verba* support for the claimed subject matter at issue. . . . The requirement is met if 'the disclosure of the application relied upon reasonably conveys to the artisan that the inventor has possession at that time of the later claimed subject matter.' *Lampi Corp. v. American Power Products, Inc.*, 56 USPQ2d 1445 (Fed. Cir. 2000).

In fact, claim 1 of this application as filed referred to hTERT protein (i.e., full-length hTERT), and fragments and variants thereof (i.e., TERT sequences having a degree of homology with hTERT). Claim 2 of the application as filed contemplated nucleic acids encoding such hTERT protein, fragments, and variants. Claims 21, 73, and 75 were subsequently introduced, more precisely defining the protein variants as being at least 80% identical to the prototype hTERT sequence (SEQ. ID NO:2). Support for this can be found in parent application USSN 08/974,549 (of which this application is a continuation), which is now U.S. Patent 6,166,178, *inter alia* at col. 3, line 47.

Thus, the skilled reader will understand that the inventors had in their possession nucleic acids encoding polypeptides containing an amino acid sequence that is at least 80% identical to the full length of SEQ. ID NO:2, or a at the time the application was filed.

Cols. 139 and 140 of the parent '178 patent provide additional guidance as to how to compare nucleic acids and protein sequences. Comparison regions of 100 or 500 consecutive amino acids, and 85%, 90%, and 95% identity within such regions are clearly contemplated. *These features further constrain the requirement* for 80% identity with SEQ. ID NO:2. Since the inventors had possession of variants that are 80% identical to SEQ. ID NO:2, the skilled reader would not doubt that they also had possession of a subset of such variants that were closer to the prototype sequence.

Withdrawal of this rejection is respectfully requested.

Rejection of claims 101-104

These claims are objected to as failing to further limit the subject matter of the claim from which they depend (claim 75). They are also rejected under 35 USC § 112 ¶ 2 as seemingly in conflict with the requirements of claim 75.

Applicants respectfully disagree. Claim 75 and claims 101-104 all particularly point out and distinctly claim the subject matter which applicants regard as embodiments of the invention. The meaning of the terms in each claim is clear. The question of further limitation or conflict can be dealt with by evaluating whether subject matter falling within claims 101-104 are a subset of the subject matter falling within claim 75.

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The answer to this is clearly yes.

Consider the case where a TRT variant is about 80% identical to SEQ. ID NO:2, with the differences spread fairly uniformly along the length of the sequence. This variant would satisfy the requirements of claim 75, but not claims 101-104. On the other hand, a variant which is over 80% identical to the whole length of SEQ. ID NO:2, and is more closely matched with (i.e., at least 95% identical to) SEQ. ID NO:2 along at least 100 or 500 amino acid segment (e.g., in the motif regions) would satisfy both claim 75, and some or all of claims 101-104.

Since claims 101-104 cover some but not all of the species covered by claim 75, they are in proper dependent format further limiting the invention. Withdrawal of this rejection is requested.

Double patenting

Certain claims stand rejected under the doctrine of obviousness-type double patenting with respect to 6,337,200 (active hTRT variants).

Applicants respectfully disagree. The claimed subject matter in the '200 patent is a specialized subset of hTRT variants which is a patentable subset of what is disclosed in this application. The present application has an earlier priority date, a different inventive entity, and is currently owned by a different organizational entity. If the '200 patent did not share a common inventor or a common owner with the present application, double patenting would not apply. Surely it is unfair for the Office to penalize applicants for having improved their own invention, favoring improvements made by unrelated third parties.

The standards for applying obviousness-type double patenting are created in large part by the Patent Office, as a result of its own interpretation of the public policy reasons behind the double patenting doctrine. Subsequent to the decision *In re Griswold*, 150 USPQ 804 (CCPA 1966), the Office amended 37 CFR § 1.321(b) to require that terminal disclaimers stipulate common ownership of the patent and application at issue. The public policy rationale for having such a regulation was to prevent harassment of an infringer by multiple assignees, the possibility of which was raised in *In re Sui*, 105 USPQ 428 (1955).

The propriety of having the Office impose such a regulation was evaluated in *In re Joel V. Van Ornum and Peter L. Stang*, 214 USPQ 761 (CCPA 1982). The court distinguished situations such as *Pope v. Gormully*, 144 U.S. 248 (1892) where a patentee undertook to assign separate claims to different parties; from *In re Robeson*, 141 USPQ 485 (1964) and *In re Jentoft*, 157 USPQ 363 (1968),

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in which the court had given little weight to the harassment possibility because it thought that divided ownership was "a remote possibility" (*In re Ornum* at 799).

By this analysis, it would be much more fair for the Office to evaluate the possibility of harassment from multiple assignees on a case-by-case basis, and require common ownership only when necessary to prevent a *bona fide* risk that such harassment would occur.

In the present instance, Geron Corporation is owner of the '200 patent, and co-owner of the present application. Geron has an exclusive license from the other co-owner of this application, which is a non-profit academic institution. Geron is exclusively responsible for commercial development of the technology claimed in the present application, as it is for the '200 patent. Accordingly, the risk of harassment to an infringer from multiple assignees is no more than a remote possibility.

On the other hand, requiring Geron Corporation to undertaking a further ownership transaction so that the patent and application are formally co-owned and a terminal disclaimer could be filed would be to impose a serious burden. Furthermore, but for the necessity of dealing with the co-ownership requirement, no benefit would ensue from such a transaction for any of the parties involved, or for the public.

Accordingly, it is applicants' position that the Office should change its policy in this regard. Either no double patenting rejection should be made, or the Office should allow applicants to overcome the rejection by filing a terminal disclaimer *that does not require co-ownership* of this application with the '200 patent.

Withdrawal of this rejection is respectfully requested.

Certain claims stand provisionally rejected for double patenting in view of what is claimed in USSN 09/438,486 (now U.S. Patent 6,927,285) and USSN 10/054,295 (now U.S. Patent 6,921,664). Without acquiescing that the claims in this application are obvious, applicants are submitting a Terminal Disclaimer with respect to both these patents under separate cover.

Certain claims stand provisionally rejected for double patenting in view of what is claimed in USSN 09/721,477, USSN 10/044,692, and USSN 10/877,124. These applications have not advanced through prosecution as far as the present application, and applicants predict that the present application will issue first. Accordingly, no double patenting issue arises.

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Request for Rejoinder:

Claims 80, 88, and 96 (Group V) are method claims that depend from and incorporate the limitations of product claims in the elected group (Group I). Applicants renew the request made on November 6, 2003, May 14, 2004, and December 24, 2004 that these claims be rejoined into the group under examination, upon determination that the product claims are patentable.

This is in accordance with MPEP § 821.04. The Examiner is reminded under 37 CFR § 1.56 that method claims using hTERT nucleic acids are also being prosecuted in USSN 09/432,503.

Rejoinder and allowance of all pending claims in the application is respectfully requested.

Request for Interview

Applicants respectfully request that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

In the event that the Examiner determines that there are other matters to be addressed, applicants hereby request an interview by telephone.

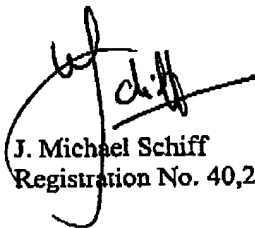
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Fees Due

Authorization is enclosed for charging the Deposit Account for the fees for the extension of time. No other fees are believed payable with respect to the filing and consideration of this paper and the accompanying documents.

However, in the event that the Patent Office determines that a further extension of time or any other relief is required for further consideration of this application, applicants hereby petition for such relief, and authorizes the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



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Facsimile Transmittal Sheet

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